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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 21, 2001, from 8 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 20B, 9200 Corporate Blvd., Rockville, MD.

Contact: Sara M. Thornton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053, SMT@CDRH.FDA.GOV, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12396. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for soft contact lenses for the correction of refractive ametropia (myopia or hyperopia) in phakic or aphakic persons with nondiseased eyes exhibiting astigmatism of 2.00 diopters (D) or less that does not interfere with visual acuity. The lenses may be prescribed for daily wear or extended wear for 1 to 30 days between removals for cleaning and disinfection or for disposal of the lens, as recommended by the eye care professional. The lens may be

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prescribed in spherical powers ranging from +20.00 D to -20.00 D. The committee will also discuss, make recommendations, and vote on a conductive keratoplasty refractive surgical device for the reduction of previously untreated spherical hyperopia in patients 40 years of age or greater, who have 0.75 D to 3.25 D of cycloplegic spherical hyperopia, with less than or equal to 0.75 D of refractive astigmatism (minus cylinder format), a cycloplegic spherical equivalent of 0.75 D to 3.00 D, and no more than 0.50 D difference between preoperative manifest refraction spherical equivalent and cycloplegic refraction spherical equivalent which shows some regression of the initial effect over time. Background information, including the agenda and questions for the committee, will be available to the public on September 20, 2001, on the Internet at http:// www.fda.gov/cdrh/panelmtg.html.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 14, 2001. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m. Near the end of the committee deliberations on each PMA, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Those desiring to make formal oral presentations should notify the contact person before September 7, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

B. Bodo 8-13-01

Dated: Aug 10, 2001

August 10, 2001.

Bonnie H. Malkin

Bonnie H. Malkin, Acting ~~Special Assistant to the~~ Senior Associate Commissioner.

B. Bodo 8-13-01

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Suzette N. Reese